



Atty. Dkt. No. 016777-0310

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Kaare M. GAUTVIK et al.

Title: PRODUCTION OF HUMAN PARATHYROID  
HORMONE FROM MICROORGANISMS

Appl. No.: 08/340,664

Filing Date: 11/16/1994

Examiner: L. Spector

Art Unit: 1647

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

**FEE**

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.


The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 10/7/04

By Ave. Zm #46,785

FOLEY & LARDNER LLP  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5143  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

 Michele M. Simkin  
Attorney for Applicants  
Registration No. 34,717

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| Substitution for form 1449B/PTO<br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(as many sheets as necessary)<br>Sheet <u>1</u> of <u>2</u> |  | <b>Complete if Known</b><br>Application Number: 08/340,664<br>Filing Date: 11/16/1994<br>First Named Inventor: Kaare M. GAUTVIK<br>Group Art Unit: 1647<br>Examiner Name: L. Spector<br>Attorney Docket Number: 016777-0310 |  |
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| U.S. PATENT DOCUMENTS |                       |                      |                                   |   |  |   |
|-----------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | U.S. Patent Document |                                   | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|                       |                       | Number               | Kind Code <sup>2</sup> (if known) |   |  |   |
|                       | A1                    | 5,208,041            |                                   | SINDREY   | 05/04/1993                                       |   |
|                       |                       |                      |                                   |   |  |   |
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| FOREIGN PATENT DOCUMENTS |                       |                         |                     |                                   |  |  |   |
|--------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|--|--|---|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document |                     |                                   | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|                          |                       | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |  |  |   |
|                          | A2                    | WO                      | 84/01173            | A1                                | IMMUNO NUCLEAR CORPORATION                       | 03/29/1984                                       |   |
|                          |                       |                         |                     |                                   |  |  |   |
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| NON PATENT LITERATURE DOCUMENTS |                       |   |  |  |
|---------------------------------|-----------------------|---|--|--|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.                                  |  |  |
|                                 | A3                    | REPPE ET AL., "Characterization of a K26Q Site-directed Mutant of Human Parathyroid Hormone Expressed in Yeast," <i>The Journal of Biological Chemistry</i> (August 5, 1991), Vol. 266, No. 22, pp. 14198-14201.  |  |  |
|                                 | A4                    | SINGH ET AL., "Synthesis, secretion and processing of $\alpha$ -factor-interferon fusion proteins in yeast," <i>Nucleic Acids Research</i> , Vol. 12, No. 23, 1984, pp. 8927-8938.  |  |  |
|                                 | A5                    | MATHAVAN ET AL., "High-level production of human parathyroid hormone in <i>Bombyx mori</i> larvae and BmN cells using recombinant baculovirus," <i>Gene</i> , Vol. 167, 1995, pp. 33-39.  |  |  |
|                                 | A6                    | NIALL ET AL., "The Amino-Acid Sequence of the Amino-terminal 37 Residues of Human Parathyroid Hormone," <i>Proc. Nat. Acad. Sci.</i> , Vol. 71, No. 2, February 1974, pp. 384-388.0.  |  |  |
|                                 | A7                    | HØGSET ET AL., "Expression of Human Parathyroid Hormone in <i>Escherichia Coli</i> ," <i>Biochemical and Biophysical Research Communications</i> (January 15, 1990), Vol. 166, No. 1, pp. 50-60.  |  |  |
|                                 | A8                    | HØGSET ET AL., "Expression and Characterization of a Recombinant Human Parathyroid Hormone Secreted by <i>Escherichia coli</i> Employing the Staphylococcal Protein A Promoter and Signal Sequence," <i>The Journal of Biological Chemistry</i> , Vol. 265, No. 13, May 5, 1990, pp. 7338-7344. |  |  |
|                                 | A9                    | KAREEM ET AL., "Translocation and processing of various human parathyroid hormone peptides in <i>Escherichia coli</i> are differentially affected by protein-A-signal sequence mutations," <i>Eur. J. Biochem.</i> (1994), Vol. 220, pp. 893-900.   |  |  |

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|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

**Complete if Known**

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|------------------------|------------------|
| Application Number     | 08/340,664       |
| Filing Date            | 11/16/1994       |
| First Named Inventor   | Kaare M. GAUTVIK |
| Group Art Unit         | 1647             |
| Examiner Name          | L. Spector       |
| Attorney Docket Number | 016777-0310      |

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| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.    | T <sup>a</sup> |
|--------------------|-----------------------|---|----------------|
|                    | A10                   | KAREEM ET AL., "A Method for the Evaluation of the Efficiency of signal Sequences for Secretion and Correct N-Terminal Processing of Human Parathyroid Hormone Produced in <i>Escherichia coli</i> ," <i>Analytical Biochemistry</i> (1992), Vol. 204, pp. 26-33. |                |
|                    | A11                   | KEUTMANN ET AL., "Isolation of Human Parathyroid Hormone," <i>Biochemistry</i> , Vol. 13, No. 8, 1974, pp. 1646-1652.   |                |
|                    | A12                   | OLSTAD ET AL., "Differences in Binding Affinities of Human PTH(1-84) Do Not Alter Biological Potency: A Comparison Between Chemically Synthesized Hormone, Natural and Mutant Forms," <i>Peptides</i> , Vol. 15, No. 7, 1994, pp. 1261-1265.                      |                |
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